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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,716	02/05/2004	Jeffrey A. Whitsett	10872.0517745	5622

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EXAMINER	
SPECTOR, LORRAINE	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/772,716	WHITSETT, JEFFREY A.	
	Examiner	Art Unit	
	Shulamith H. Shafer, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim(s) 1 in part, 2 in part, 4, 17-24 in part, drawn to a method of treating pulmonary disease by administration of a FoxA2 protein, classified in class 514, subclass 2.

II. Claim(s) 1 in part, 2 in part, 5-16, 17-24 in part, drawn to a method of treating pulmonary disease by administration of a nucleic acid encoding a FoxA2 protein, classified in class 514, subclass 44.

III. Claim(s), 1 in part, 2 in part, 3, 17-24 in part, drawn to a method of treating pulmonary disease by administration of a FoxA2 receptor-specific antibody protein classified in class 424, subclass 130.1.

IV. Claim(s) 25 in part, 26 in part, drawn to method of prescribing treatment and a method of prophylactically treating airway hyperresponsiveness by administration of a FoxA2 protein, classified in class 514, subclass 2.

V. Claim(s) 25 in part, 26 in part, to drawn to method of prescribing treatment and a method of prophylactically treating airway hyperresponsiveness by administration of a nucleic acid molecule encoding a FoxA2 protein, classified in class 514, subclass 44.

VI. Claim(s) 25 in part, 26 in part, drawn to method of prescribing treatment and a method of prophylactically treating airway hyperresponsiveness by administration of a receptor-specific antibody, classified in class 424, subclass 130.1.

VII. Claim(s) 27-31, drawn to a method of improving gas exchange, classification dependent upon the recitation of the anti-inflammatory agent.

VIII. Claim(s) 32-34 in part, 40, 41-43 in part, drawn to a formulation for protecting a mammal from airway hyperresponsiveness comprising an

anti-inflammatory agent and a FoxA2 receptor-specific antibody, classified in class 530, subclass 387.1.

IX. Claim(s) 32-34 in part, 35, 41-43 in part, drawn to a formulation for protecting a mammal from airway hyperresponsiveness comprising an anti-inflammatory agent and a FoxA2 protein, classified in class 530, subclass 350.

X. Claim(s) 32-34 in part, 36-39, 41-43 in part, drawn to a formulation for protecting a mammal from airway hyperresponsiveness comprising an anti-inflammatory agent and a nucleic acid molecule encoding a FoxA2 protein, classified in class 536, subclass 23.5.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons. The methods of Inventions I-VII have different intended uses, goals, starting and ending points and require different method steps. The methods of Inventions I-III are drawn to a method of treatment of an unspecified pulmonary disease, while the methods of Inventions IV-VI are drawn to methods of treatment of a particular symptom of specific pulmonary diseases, airway hyperresponsiveness, and the methods of Invention VII are drawn to improvement of gas exchange. The search for these methods in the same application would not be co-extensive and would present a serious burden to the examiner and the resources of the USPTO. While the methods of Inventions I-III are all drawn to a method of treating an unspecified pulmonary disease, each of the inventions recites a different therapeutic agent; Invention I recites administration of a FoxA2 protein, Invention II recites administration of nucleic acid molecule encoding a FoxA2 protein, and Invention III recites administration of a FoxA2 receptor-specific antibody. Therefore, a search for all three of these methods in the same application would present

a serious burden to the examiner and resources of the USPTO. Inventions IV-VI are all drawn to treatment of airway hyperresponsiveness, but each utilizes a different therapeutic agent; Invention IV recites administration of a FoxA2 protein, Invention V recites administration of nucleic acid molecule encoding a FoxA2 protein, and Invention VI recites administration of a FoxA2 receptor-specific antibody. Therefore, a search for all three of these methods in the same application would present a serious burden to the examiner and resources of the USPTO.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these groups constitute patentably distinct inventions for the following reasons. Inventions VIII-X are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct.

The protein of formulation of Invention IX and the nucleic acid of the formulation of Invention X are patentably distinct for the following reasons: polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polypeptide and polynucleotide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Furthermore, searching the inventions of Inventions IX and X together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides is not coextensive. The inventions of Inventions IX and X have a separate status in the art as shown by their different classifications.

The protein of Invention IX and the antibody of Invention VIII are patentably distinct for the following reasons: while the inventions of both Inventions I and II are polypeptides, in this instance, the polypeptide of Invention IX is a single chain molecule, whereas the polypeptide of Invention VIII encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions,

including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs) that function to bind an epitope. Thus, the polypeptide of Invention IX and the antibody of Invention VIII are structurally distinct molecules. Therefore, the polypeptide and antibody are patentably distinct.

Furthermore, searching the inventions VIII and IX would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications.

The polynucleotide of Invention X and the antibody of Invention VIII are patentably distinct for the following reasons: the antibody of Invention VIII includes, for example, IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs). Polypeptides, such as the antibody of Invention VIII which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules. Therefore, the antibody and polynucleotide are patentably distinct. The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions VIII and X would impose a serious search burden since a search of the polynucleotide of Invention X would not be used to determine the patentability of an antibody in formulation of Invention VIII and vice-versa.

Inventions I-VII and VIII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the formulations of Inventions VIII-X are not made by or utilized in the methods of Inventions I-VII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and separate search requirements, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

This application contains claims directed to the following patentably distinct species: pulmonary disease. The species are independent or distinct because they are distinct medical conditions having different etiologies and effects.

a. airway obstruction
b. allergies
c. asthma
d. acute inflammatory lung disease
e. chronic obstructive pulmonary dysplasia
f. emphysema, pulmonary emphysema
g. chronic obstructive emphysema

h. adult respiratory distress syndrome
i. bronchitis
j. chronic bronchitis
k. chronic asthmatic bronchitis
l. chronic asthmatic bronchitis
m. chronic obstructive bronchitis
n. interstitial lung diseases
o. allergic bronchopulmonary aspergillosis
p. hypersensitivity pneumonia
q. eosinophilic pneumonia
r. allergic bronchitis
s. bronchiectasis
t. hypesensitivity pneumotitis
u. occupational asthma
v. reactive airway disease syndrome
w. hypereosinophilic syndrome
x. rhinitis
y. sinusitis
z. parasitic lung disease

If Applicant elects any one of **Inventions I-III**, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (**a-z**) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 2 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

This application contains claims directed to the following patentably distinct species: anti-inflammatory agent. The species are independent or distinct because they are distinct compounds or molecules having different effects and modes of action.

1. anti-IgE
2. immunomodulating drugs
3. leukotriene synthesis inhibitors
4. glucocorticosteroid
5. steroid chemical derivatives
6. anti-cylooxygenase agents
7. beta-adrenergic agonists
8. methylxanthines
9. cromones
10. anti-CD4 reagents
11. anti-IL-5 reagents
12. surfactants
13. cytoxin
14. heparin

If Applicant elects any one of **Inventions VII-X**, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (**1-14**) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 27, and 32 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims

readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shulamith H. Shafer, Ph.D. whose telephone number is 571-272-3332. The examiner can normally be reached on Monday through Friday, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SHS

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER